JAN 18 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K111221.

Submitter's Identification:

ACON Laboratories, Inc.
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San Diego, CA 92121

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Date Prepared: December 29, 2011

Contact Person:

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Proprietary Name of the Device:

Mission® U500 Urine Analyzer

Common Name:

Urine Chemistry Analyzer

Regulation Section and Classification:

21 CFR § 862.2900	Automated Urinalysis System
21 CFR § 862.1340	Urinary Glucose (Non-Quantitative) Test System
21 CFR § 864.6550	Occult Blood Test
21 CFR § 862.1115	Urinary Bilirubin and its Conjugates (Non-Quantitative) Test System
21 CFR § 862.1435	Ketones (Non-Quantitative) Test System
21 CFR § 862.1550	Urinary pH (Non-Quantitative) Test System
21 CFR § 862.1645	Urinary Protein or Albumin (Non-Quantitative) Test System
21 CFR § 862.1785	Urinary Urobilinogen (Non-Quantitative) Test System

21 CFR § 862.1510 Nitrite (Non-Quantitative) Test System
21 CFR § 864.7675 Leukocyte Peroxidase Test
21 CFR § 862.1095 Ascorbic Acid Test System
21 CFR § 862.2800 Refractometer for Clinical Use

Class I: Automated Urinalysis System; Urinary Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen, Urinary Bilirubin, Specific Gravity and Ascorbic Acid

Class II: Urinary Glucose and Occult Blood

Product Code:

KQO	Automated Urinalysis System
JIL	Urinary Glucose (non-quant.) test system
JIO	Blood, Occult, Colorimetric, in urine
LJX	Test, Urine Leukocyte
CEN	Urinary, pH (non-quant.)
JMT	Nitrite (urinary, non-quant.) test system
JIR	Protein or Albumin (urinary, non-quant.) test system
JIN	Ketones (urinary, non-quant.) test system
CDM	Urinary Urobilinogen (non-quant.) test system
JJB	Urinary Bilirubin & its conjugates (urinary, non-quant.) test system
JMA	Acid, Ascorbic, 2, 4-Dinitrophenylhydrazine (Spectrophotometric)
JRE	Refractometer clinical use

Medical Specialty:

Clinical Chemistry

Predicate Device:

ACON U120 Urine Analyzer, ACON Laboratories, Inc, marketed by ACON laboratories, Inc located at 10125 Mesa Rim Road, San Diego, CA 92121, USA.

510(k) Number: K070929

Description:

The Mission® U500 Urine Analyzer is a semi-automated reflectance photometer in conjunction with Mission Urinalysis Reagent Strips (originally cleared under k061559) that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. The analyzer throughput is 500 tests per hour and the measuring cycle is 7 seconds per test. The analyzer stores up to 2,000 patient records and prints the results in Conventional, SI, or Arbitrary units using an integrated internal or external printer.

Test Format and Configurations:

1) Mission® U500 Urine Analyzer, 1 Strip Platform/Waste Tray, 2 Printer Paper Rolls, 2 Fuses, 1 Power Cord, 1 Instruction Manual;

2) Mission® U500 Urine Analyzer, 1 Strip Platform/Waste Tray, 2 Printer Paper Rolls, 1 Barcode Reader, 1 Serial Splitter Cable, 2 Fuses, 1 Power Cord, 1 Instruction Manual

The following components are available separately: Printer Paper Rolls, Barcode Reader, Data Transfer Kit, and Fuses.

Compatible Urinalysis Reagent Strips (default):

# of Parameters	Catalog No.	Type of Strip	Analytes
8	U031-081	8N	Leukocytes, Nitrite, Protein, pH, Blood, Specific Gravity, Ketone and Glucose
9	U031-091	9U	Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
10	U031-101	10U	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
11	U031-111	11A	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose and Ascorbic Acid

Note: Only use strips of the same brand as the analyzer to ensure proper function and accurate results.

Above configurations shown for 8 through 11 parameters are available as options. Other compatible strip configurations are available with combinations between 1 and 11 parameters from the label below, as defined in the analyzer selectable strip configuration settings. The strip configuration is factory-fixed for each analyzer and is reflected in the user manual.

Analyzer-read Strips: xx/xx/xx/xx

The Mission Urinalysis Reagent Strips have been cleared for visually reading by comparison to a color chart and the Mission Urinalysis Reagent Strips can be sold in any combination of 1 or more of the following 11 analytes (k061559).

Glucose	Bilirubin
Ketone	Urobilinogen
Specific Gravity	Nitrite
Blood	Leukocyte
pH	Ascorbic Acid
Protein	

Combination from the 11 parameters can be read on the Mission U500 Urine Analyzer (Catalog # U211-111, U211-101). The following list shows current combinations, additional combinations can be available based on customer request.

Additional Compatible *Mission*® Urinalysis Reagent Strips

Product Name	No. of Parameters	Type of Strip	Analytes
Mission® Urine Analysis Strip U031-111	**11**	**11A**	**Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose and Ascorbic Acid**
Mission® Urine Analysis Strip U031-101	**10**	**10U**	**Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose**
		10A	**Ascorbic Acid, Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite**
Mission® Urine Analysis Strip U031-091	**9**	**9U**	**Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose**
Mission® Urine Analysis Strip U031-081	**8**	**8U**	**Glucose, Bilirubin, Ketone, Blood, pH, Protein, Urobilinogen, Nitrite**
		8N	**Leukocytes, Nitrite, Protein, pH, Blood, Specific Gravity, Ketone and Glucose**
		8S	**Glucose, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes**
		8K	**pH, Glucose, Bilirubin, Protein, Urobilinogen , Nitrite, Leukocytes, Ketone**
Mission® Urine Analysis Strip U031-071	**7**	**7N**	**Glucose, Ketone, Blood, pH, Protein, Nitrite, Leukocytes**
Mission® Urine Analysis Strip U031-061	**6**	**6NE**	**Glucose, Blood, pH, Protein, Nitrite, Leukocytes**
		6UE	**Bilirubin, Specific Gravity, Blood, Protein, Urobilinogen, Nitrite**
Mission® Urine Analysis Strip U031-051	**5**	**5BE**	**Glucose, Ketone, Blood, pH, Protein**
		5NE	**Glucose, Blood, Protein, Nitrite, Leukocytes**
		5SE	**Glucose, Specific Gravity, Blood, pH, Protein**
		5UE	**Bilirubin, Blood, Urobilinogen, Nitrite, Leukocytes**
Mission® Urine Analysis Strip U031-141	**4**	**4SE**	**Glucose, Specific Gravity, pH, Protein**
		4BE	**Glucose, Blood, pH, Protein**
		4KE	**Glucose, Ketone, pH, Protein**
		4GE	**Glucose, Blood, Protein, Leukocytes**
		4NE	**Blood, Protein, Nitrite, Leukocytes**
		4PE	**Glucose, Protein, Nitrite, Leukocytes**
Mission® Urine Analysis Strip U031-031	**3**	**3PE**	**Glucose, pH, Protein**
		3KE	**Glucose, Ketone, Protein**
		3GE	**Glucose, Ketone, pH**
		3NE	**Blood, Nitrite, Leukocytes**
Mission® Urine Analysis Strip U031-021	**2**	**2GE**	**Glucose, Protein**
		2KE	**Glucose, Ketone**
		2NE	**Nitrite, Leukocytes**
		2BE	**Blood, Leukocytes**
		2UE	**Bilirubin, Urobilinogen**
		2SE	**Specific Gravity, pH**
Mission® Urine Analysis Strip U031-011	**1**	**1BE**	**Blood**
		1PE	**pH**
		1GE	**Glucose**
		1KE	**Ketone**
		1RE	**Protein**

Intended Use:

The Mission® U500 Urine Analyzer is intended for use in conjunction with the Mission® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection Nitrite. The instrument is intended for prescription, for in vitro diagnostic use only. Mission Urinalysis Reagent Strips are available in different test configurations and the measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

Technological Characteristics:

Feature	Specifications
Intend of use	For Prescription, In Vitro Diagnostic Use Only
Testing Specimen	Urine
Detection	Photosensitive diode
Detection Methodology	Reflectance Photometer
Wavelength	525 nm and 635 nm (nominal)
Analyzer Operation Conditions	0-40°C (32-104°F); ≤85% Relative Humidity (non-condensing)
Strips to be used	Mission® Urinalysis Reagent Strips
Strip Operating Conditions	15-30°C (59-86°F); ≤85% Relative Humidity (non-condensing)
Calibration	Automatic
Power Source	100-240 VAC, 50-60 Hz
Line Leakage Current	<3.5 mA (single fault)
Data Transfer	Standard RS232C Port
Capabilities	Internal printer (included) 25 Pin Parallel External Printer Port connector (included) Barcode Reader (optional)
Available Languages on Screen	English(default), Spanish, French (others as installed)
Throughput	500 tests/hour
Measuring Cycle	7 seconds/test
Strip Incubation Time	1 minute
Memory	2,000 results
Waste Disposal Capacity	Up to 150 strips
Dimensions	35.5 cm x 27.4 cm x 19.5 cm (14" x 10.8" x 7.7")
Display Dimensions	11.5 cm × 9.0 cm (4.5" x 3.5")
Weight	4.0 kg (8.82 lbs)

Comparison to Predicate Devices:

The Mission® U500 Urine Analyzer is substantially equivalent to the ACON U120 Urine Analyzer originally cleared under k070929.

Feature	Mission® U500 Urine Analyzer	ACON U120 Urine Analyzer (k070929)
Similarities		
Intend of use	For Prescription, In Vitro Diagnostic Use Only	Same
Testing Specimen	Urine	Same
Detection	Photosensitive diode	Same
Detection Methodology	Reflectance Photometer	Same
Wavelength	525 nm and 635 nm (nominal)	Same
Analyzer Operation Conditions	0-40°C (32-104°F); ≤85% Relative Humidity (non-condensing)	Same
Strips to be used	Mission® Urinalysis Reagent Strips	Same
Strip Operating Conditions	15-30°C (59-86°F); ≤85% Relative Humidity (non-condensing)	Same
Strip Incubation Time	1 minute	Same
Calibration	Automatic	Same
Power Source	100-240 VAC, 50-60 Hz	Same
Line Leakage Current	<3.5 mA (single fault)	Same
Data Transfer	Standard RS232C Port	Same
Capabilities	Internal printer (included) 25 Pin Parallel External Printer Port connector (included) Barcode Reader (optional)	Same
Available Languages on Screen	English(default), Spanish, French (others as installed)	Same
Differences		
Throughput	500 tests/hour	Single Test Mode: 40 tests/hour, Continuous Test Mode: 120 test/hour
Measuring Cycle	7 seconds/test	20 seconds/test
Memory	2,000 results	Last 500 results
Waste Disposal Capacity	Up to 150 strips	Manually at each test
Dimensions	14"(L) x 10.8"(W) x 7.7"(H) (35.5 x 27.4 x 19.5)cm	10.7"(L) x 10.4"(W) x 5.8"(H) (27.1 x 26.5 x 14.8) cm
Display Dimensions	4.5"(W) x 3.5" (H) (11.5 × 9.0) cm	4.2"(W) x 1.1"(H) (10.6 x 2.8) cm
Weight	8.82 lbs (4.0 kg)	5.73 lbs (2.6 kg)

Summary of Performance Data:

Performance studies were conducted in-house and in a clinical setting to establish the performance of the Mission® U500 Urine Analyzer and to demonstrate substantial equivalence to the predicate device. Analytical and clinical performance studies are summarized below. In addition, software documentation and a summary of electromagnetic compatibility and electrical safety testing are included to provide additional evidence of device performance.

Analytical Performance Testing:

The performance characteristics of the Mission® U500 Urine Analyzer were evaluated by the following studies: analytical sensitivity and detection range, reproducibility, interfering substances, temperature flex, humidity flex, voltage flex, and reagent strip stability.

Clinical Performance Testing:

Clinical performance of the Mission® U500 Urine Analyzer was evaluated in a method comparison study between the Mission® U500 Urine Analyzer and ACON U120 Urine Analyzer predicate device. Clinical study data are presented for the percent positive agreement, percent negative agreement, and percent agreement on and between color blocks results indicate that the intended users were able to obtain comparable testing results when using the Mission® U500 Urine Analyzer and the legally marketed ACON U120 Urine Analyzer both in conjuction with the Mission® Urine Analysis Reagent Strips (originally cleared under k061559).

Conclusion:

The nonclinical and clinical performance study results demonstrate that the Mission® U500 Urine Analyzer, as designed and manufactured, is substantially equivalent to the predicate device Mission® U120 Urine Analyzer (originally cleared under k070929).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

ACON LABORATORIES, INC
c/o Qiyi Xie
10125 Mesa Rim Rd
San Diego, CA 92121

JAN 18 2012

Re: k111221
Trade Name: Mission U500 Urine Analyzer
Regulation Number: 21 CFR §864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Codes: JI0, JIL, CDM, JJB, JIN, JIR, NGJ, LJX, CEN, JMA, JRE, KQO
Dated: December 29, 2011
Received: December 30, 2011

Dear Qivi Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k111221

Device Name: Mission® U500 Urine Analyzer

Indications for Use:

The Mission® U500 Urine Analyzer is intended for use in conjunction with the Mission® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes and Ascorbic Acid as well as the qualitative detection Nitrite. The instrument is intended for prescription, for in vitro diagnostic use only. Mission Urinalysis Reagent Strips are available in different test configurations and the measurement can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 111221